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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,433	02/16/2006	Michael Goldberg	817.1013US	9801

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EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1654	

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02/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,433	GOLDBERG ET AL.	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22,24,25,27-29,33-38 and 40-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22,24,25,27-29,33-38 and 40-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Pursuant to the directives of the response filed 11/28/07, several claims have been amended. Claims 1-22, 24, 25, 27-29, 33-38, 40-67 remain pending.

✧

Claims 1, 16, 34, 66 are objected to.

Claim 1 recites the following:

"a pharmaceutically acceptable delivery agent 4-CNAB"

The phrase "pharmaceutically acceptable delivery agent" is superfluous in this claim, but that is beside the point. The point is that the phrase referred to is grammatically incorrect. One option would be the following:

> *...comprising orally administering.... a formulation comprising insulin and 4-CNAB in an amount effective to facilitate absorption of the insulin from the GI tract...[etc.]*

Claim 66 recites the following: "wherein said pharmaceutically acceptable delivery agent 4-CNAB". However, this is grammatically incorrect. The same issue applies in the case of claims 16, 34 and 66.

✧

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 29 is rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As indicated previously, claim 29 recited the phrase "prophylactically sparing" beta cell function. Now the claim recites "prophylactically reducing". First, it is not at all clear why one would want to harm a patient by deliberately impairing his (or her) *beta* cell function. But assuming that applicants can come up with a reason for this, the claim still recites the term "prophylactically", which is not enabled.

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

Accordingly, "undue experimentation" would be required to practice the claimed invention.

✧

Claims 25, 48, 66, 67 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims recite that the delivery agent "comprises" 4-CNAB. Certainly, there are several references to CNAB in the specification. However, what is described is an agent which **is** 4-CNAB, not an agent that "comprises" CNAB. There may also be descriptive support for a pharmaceutical composition that comprises insulin and CNAB, but again, there is no support for a delivery agent "comprises" 4-CNAB. [It is noted that claim 33 as filed did recite the term "comprises" in reference to CNAB. However, the invention referred to in that claim is different from the invention of instant claim 1].

Unrelated to the foregoing is the phrase "prophylactically reducing" in claim 29. Applicants are requested to point to the location where support can be found.

✧

Claims 1-22, 24, 25, 27-29, 33-38, 40-67 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 recites the following:

"a pharmaceutically acceptable delivery agent 4-CNAB"

At the same time, claim 1 also recites that the 4-CNAB facilitates absorption of the insulin from the GI tract. One of the two phrases are thus redundant. In traversing, applicants are requested to provide a few examples of compounds that are used in pharmaceutical compositions to facilitates absorption of a drug from the GI tract, but which compound does not, at the same time, qualify as a "delivery agent". (These examples will provide the basis for further discussion). The same issue applies in the case of claims 16, 25, and 34.

- As applicants will no doubt argue, claim 1 mandates that the delivery agent can be nothing more and nothing less than 4-CNAB. The examiner disagrees with this assessment, but that is beside the point. The point is that if indeed claim 1 does mandate that the delivery agent can be nothing more and nothing less than 4-CNAB, then claim 33 is not properly subgeneric thereto, since it recites that the agent comprises 300 mg 4-CNAB. The same issue applies in the case of claim 67 versus 34.

- Claims 46 and 65 are not properly subgeneric to claims 25 or 34. Claims 25 and 34 are limited to a specific delivery agent, whereas claims 46 and 65 permit any delivery agent. One option would be to cast claims 46 and 65 in independent form.

- In claim 66, the phrase "said mammals" lacks antecedent basis, since "mammals" is being used in the plural.

✧

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 46 and 65 are rejected under 35 U.S.C. §103 as being unpatentable over Pilarski (USP 7,137,951) in view of Byrd (USP 7,118,762) or Moye Sherman (USP 7,115,663) or Ekwuribe (USP 7,084,114) or Ekwuribe (USP 7,060,675).

Pilarski discloses (col 30, line 59) administration of insulin at bedtime. Pilarski does not specify oral administration. Each of the secondary references discloses orally administrable forms of insulin.

Thus, it would have been obvious to use one of the orally administrable forms of insulin for the advantages cited therein.

The cited claims can be interpreted to mean that any absorption-enhancing agent can be used, not just 4-CNAB. As such, the claims are rendered obvious.

✧

Claims 46 and 65 are rejected under 35 U.S.C. §103 as being unpatentable over Ekwuribe (USP 7060675).

Ekwuribe discloses (e.g., col 4, line 10; col 4, line 45) orally administrable insulin. Also disclosed (col 11, line 65) is administration at bedtime.

Thus, the claims are rendered obvious.

✧

Claims 46 and 65 are rejected under 35 U.S.C. §103 as being unpatentable over Miller J. L. (*Clinical Pharmacology and Therapeutics* 53(3), 380-4, 1993) in view of (a) Mesiha Mounir S. (*International Journal of Pharmaceutics* 249(1-2), 1-5, 2002) or (b) Hosny Ehab A. (*International Journal of Pharmaceutics* 237(1-2), 71-6, 2002) or (c) Clement Stephen (*Diabetes Technology & Therapeutics* 4(4), 459-66, 2002).

Miller discloses that administering insulin at bedtime is beneficial. Miller does not disclose oral administration of insulin. However, each of the secondary references discloses orally administrable insulin, and the benefits associated therewith.

Accordingly, it would have been obvious to one of ordinary skill to use orally administrable insulin at bedtime.

✧

Claims 46 and 65 are rejected under 35 U.S.C. §103 as being unpatentable over Yki-Jarvinen H. (*Annals of internal medicine* 130(5), 389-96, 1999) in view of (a) Mesiha Mounir S. (*International Journal of Pharmaceutics* 249(1-2), 1-5, 2002) or (b) Hosny Ehab A. (*International Journal of Pharmaceutics* 237(1-2), 71-6, 2002) or (c) Clement Stephen (*Diabetes Technology & Therapeutics* 4(4), 459-66, 2002).

Yki-Jarvinen discloses that administering insulin at bedtime is beneficial. Yki-Jarvinen does not disclose oral administration of insulin. However, each of the secondary references discloses orally administrable insulin, and the benefits associated therewith.

Accordingly, it would have been obvious to one of ordinary skill to use orally administrable insulin at bedtime.

✧

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DAVID LUKTON, PH.D.
PRIMARY EXAMINER